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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,205	05/06/2004	Christopher E. Banas	6006-157	7254

7590 12/13/2007

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EXAMINER	
GANESAN, SUBA	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

mN

Office Action Summary	Application No.	Applicant(s)	
	10/840,205	BANAS ET AL.	
	Examiner	Art Unit	
	Suba Ganesan	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4 and 13-15, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al (WO 01/74274 A2).

3. Palmaz et al discloses an implantable medical graft, comprising: a. a generally tubular body member comprising a film selected from the group consisting of metallic and pseudometallic materials (page 17, lines 1-7); and b. at least a portion of the body member having a plurality of undulations formed in walls of the body member by a

support arranged in any manner as is known in the art of stent fabrication (page 5, lines 16-20), and microperforations (e.g. Figs. 2-3 and 8A-8C). However, Palmaz et al does not disclose the support arranged ***specifically*** as having continuous circumferential undulations. Palmaz et al also discloses (page 5, lines 13-25): "In accordance with one of the embodiments of the present invention, there is provided a stent-graft-type device, termed a "web-stent" in which there is at least one of a plurality of structural members that provide a primary means of structural support for the webbed-stent device. The plurality of structural members may be arranged in any manner as is known in the art of stent fabrication, e.g., single element ***forming a circle or ellipse, a single or plural elements which form a tubular diamond-like or undulating pattern***, in which adjacent structural members are spaced apart forming open regions or interstices between adjacent structural members" (emphasis added). It would be obvious to one of ordinary skill in the art that the use of a plurality of single elements that each a form a circle would result in a medical graft having continuous circumferential undulations, the motivation being: it would be obvious to try in view of the disclosure of the possible configuration in Palmaz.

4. Claims 5, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al, in view of Van Schie et al (6,974,471 B2).

5. Palmaz et al discloses an implantable medical graft as above. However, Palmaz et al does not disclose at least one suture member integrally extending along the

longitudinal axis and through suture holes. Van Schie et al teaches an implantable medical graft comprising at least one suture member integrally extending along the longitudinal axis and through suture holes (e.g. Figs 4 and 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of at least one suture member integrally extending along the longitudinal axis and through suture holes, as taught by Van Schie et al, to an implantable medical graft as per Palmaz et al, in order so that "the device can be curved insitu to fit the curved lumen" as found in Van Schie et al (col. 1, lines 44-52).

6. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al in view of Van Schie et al as above, and in further view of Kula et al (6,325,825 B1).

7. Palmaz et al/ Van Schie discloses an implantable medical graft as above. However Palmaz et al/ Van Schie does not disclose the thickness of the undulating regions as less than that of the non-undulating regions. Kula et al teaches an implantable medical graft having thicker ends, which correspond to the non-undulating regions of Palmaz et al/ Van Schie (col. 4, lines 60-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of an implantable medical graft having thicker ends, as taught by Kula et al, to an implantable medical graft as per Palmaz et al/ Van Schie, in order to "protect the artery and any plaque from abrasion that may be caused by the stent 10 ends during

insertion of the stent 10. The modification also may provide increased radio-opacity at the ends of the stent 10. Hence it may be possible to more accurately locate the stent 10 once it is in place in the body" as found in Kula et al (col. 4, lines 60-66).

Regarding claim 7 Palmaz et al/ Van Schie in further view of Kula et al fail to disclose the **specific** thicknesses of the claimed regions. However, Palmaz et al discloses that the thickness of the microperforated material is approximately 10 micrometers (page 21, lines 13-14). Palmaz et al also discloses that the undulations may be formed by a "subtractive" method (Fig. 10). The reduction of the undulation region relative to the non-undulated region would result in a thickness of the thinner region ***about*** 3-7 micrometers.

8. With respect to claims 9 and 10, Palmaz et al/ Van Schie/Kula fail to disclose the suturing openings as cruciform or generally Y-shaped slots. At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make the slots these shapes. Applicant has not disclosed that these shapes provides an advantage, is used for a particular purpose, or solve a stated problem, and therefore appear to be a matter of obvious design choice. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the holes of Van Schie et al or the claimed slots because both allow for the passage of sutures. Furthermore such shaped holes for sutures are known in the art (Moser U.S. Pat. No. 5725556). Therefore, it would have been obvious to one of ordinary skill in the art to modify the cited references to obtain the invention as specified

in claims 9 and 10. Please note that the Applicant may have intended to claim the microperforations as cruciform or generally Y-shaped slots.

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz et al as above in view Banas et al (5,749,880).

10. Palmaz et al discloses an implantable medical graft as above. However Palmaz et al does not disclose the implant having barbs. Banas et al teaches an implantable medical graft having projecting barb members (col. 14, lines 48-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teaching of projecting barb members, as taught by Banas et al, to an implantable medical graft as per Palmaz et al, in order to aid in anchoring to the target blood vessel wall, as in Banas et al (col. 14, lines 48-54).

Response to Arguments

1. Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive. The 103 rejection of Palmaz in view of Hess was modified to be a 103 rejection based on Palmaz alone because sufficient teaching was present in the Palmaz application by itself to render the claimed invention obvious. Palmaz states: "In accordance with one of the embodiments of the present invention, there is provided a stent-graft-type device, termed a "web-stent" in which there is at least one of a plurality of structural members that provide a primary means of structural support for the

webbed-stent device. The plurality of structural members may be arranged in any manner as is known in the art of stent fabrication, e.g., single element ***forming a circle or ellipse, a single or plural elements which form a tubular diamond-like or undulating pattern***, in which adjacent structural members are spaced apart forming open regions or interstices between adjacent structural members" This statement indicates that the stent structure can have a plurality of continuous circumferential undulations with peaks and valleys: Taking this teaching in Palmaz literally, the number of structural members 42 in Figures 6 can be increased to more than just two. Adjacent structural members 42 spaced apart to yield peaks (ie. where a structural member is present) or a valleys (ie, Where a structural member is absent); this defines continuous circumferential undulations. Using the teaching for circular spaced apart structural elements, one of ordinary skill in the art could modify the stent of Palmaz to include a plurality of circumferentially extending continuous undulations with peaks and valleys with predictable results. The rejection is proper and therefore maintained.

2. With respect to the rejections of claims 5-12 and 16, the intended use carries no weight in the absence of distinguishing structure. Van Schie et al teaches an implantable medical graft comprising at least one suture member integrally extending along the longitudinal axis and through suture holes (e.g. Figs 4 and 6).

3. With respect to claims 6-10, the non-undulating portions of Palmaz are located at either end of the stent. Kona provides reasoning for increasing the thickness of the ends of the stent. When combined with Palmaz, this yields thicker non-undulating portions. With respect to claim 7, the claim language "about" broadens the range to encompass a

thickness of 10 micrometers. With respect to claims 9-10, a teaching for Y shaped connectors has been provided.

Conclusion

4. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suba Ganesan whose telephone number is 571-272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SDG 12/10/2007

/William H. Matthews/
Primary Examiner
AU 3774